

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICANT : | Schrepfer, <i>et al.</i> | CONFIRMATION NO. : | 8751 |
| SERIAL NUMBER : | 09/980,661 | EXAMINER : | Robert L. Nasser |
| FILING DATE : | October 2, 2003 | ART UNIT : | 3735 |
| FOR : | METHOD AND DEVICE FOR DETERMINING THE CONCENTRATION OF A SUBSTANCE IN BODY LIQUID | | |

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**UNDER 37 C.F.R. §1.705(b)**

Applicants request reconsideration of patent term adjustment for the above-referenced application. Also enclosed is the two-hundred dollar fee as required by 37 C.F.R. § 1.18(e).

Applicants received a Notice of Allowance and Fees Due from the U.S. Patent and Trademark Office, mailed on September 1, 2009, which stated that the Patent Term Adjustment under 35 U.S.C. 154(b) to date is 598 days. This Request is submitted in view of Applicants' duty under 37 C.F.R. 1.765 as well as the decision by the U.S. District Court decision in *Wyeth v. Dudas* (D.D.C. 2008) on September 30, 2008.

Applicants note that the Patent Term Adjustment associated with the filing the Response to Notification of Missing Requirements was not accounted for in the Office's Patent Term Adjustment calculation. In accordance with 37 C.F.R. 1.765, Applicants' duty of candor and good faith toward the Office, Applicants submit that the Patent Term Adjustment should have an additional 51 days of Applicant delay in connection with this filing.

By this paper, Applicants hereby petition the U.S. Patent and Trademark Office for reconsideration of the patent term adjustment calculation to **1186 days**, based on the facts provided herein.

The National Stage of the instant application commenced under 35 U.S.C. §371 (b)/(f) on November 15, 2001, and is therefore subject to the patent term adjustment procedures set forth in 37 C.F.R. §§ 1.702 to 1.705 for applications filed on or after May 29, 2000.

On May 12, 2003, the Office mailed a Notification of Missing Requirements.

On October 2, 2003, Applicants filed a Response to Notification of Missing Requirements with a three month extension of time and satisfied the requirements of 35 U.S.C. 371. This Response was filed 51 days after the date that is three months after the mailing date of the Notification. As discussed above, in accordance with 37 C.F.R. 1.765, Applicants' duty of candor and good faith toward the Office, Applicants submit that the Patent Term Adjustment should have an additional **51 days** of Applicant delay in connection with this filing.

On January 17, 2007, the Office mailed a Non-Final Office Action. The Action was mailed 776 days after the fourteen month requirement for mailing of the first action after the date on which the application fulfilled the requirements of 35 U.S.C. §371. As shown in the PAIR printout submitted as Exhibit A, the number of days of Patent Term Adjustment accounts for the 776 day Office delay.

On May 15, 2007, Applicants filed a Response to the Non-Final Office Action with a one month extension of time. This Response was filed 28 days after the date that is three months after the mailing date of the Action. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 28 day Applicant delay.

On August 9, 2007, the Office mailed a Non-Final Office Action. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On October 30, 2007, Applicants filed a Response to Non-Final Office Action. This Response was received within three months of the mailing date of the Action.

On January 24, 2008, the Office mailed a Notice of Non-Responsive Amendment that indicated the Response filed on October 30, 2007 was non-responsive.

On March 19, 2008, Applicants filed a Response to the Notice of Non-Responsive Amendment mailed on January 24, 2008, which is the reply by Applicants that corrects the omission under 37 CFR 1.704(c)(7) made in the response filed on October 30, 2007. Applicants submit that the delay under 1.704 should be counted from the day after the date the reply having an omission was filed, *i.e.* October 31, 2007, and ending on the date that the reply or other paper correcting the omission was filed, *i.e.* March 19, 2008. Thus, the number of days of Applicant delay is 141 days. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 141 day Applicants delay.

On June 27, 2008, the Office mailed a Final Office Action. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On October 1, 2008, Applicants filed a Request for Continued Examination with a one month extension of time. This Request was filed 4 days after the date that is three months after the mailing date of the Final Office Action. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 4 day Applicant delay.

On December 22, 2008, the Office mailed a Non-Final Office Action. This Action was mailed within the four months of the filing of the reply filed under 35 U.S.C. §132.

On April 14, 2009, Applicants filed a Response to the Non-Final Office Action with a one month extension of time. This Response was filed 23 days after the date that is three months after the mailing date of the Non-Final Office Action. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 23 day Applicant delay.

On September 1, 2009, the Office mailed the Notice of Allowance/Notice of Allowability, and the Determination of Patent Term Adjustment for this application. The Notice was mailed 18 days after the four month requirement for the USPTO to respond to a reply filed under 35 U.S.C. §132. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 18 day Office delay. The Determination of Patent Term Adjustment noted an adjustment period for this patent application of 598 days.

According to the provisions of 37 C.F.R. §1.702(b), Applicants are entitled to Patent Term Adjustment for the failure of the Office to issue the patent within three years after the date on which the application was filed. Under 37 C.F.R. §1.702(b)(1)-(5), Applicants are entitled to this adjustment for any time other than time consumed by continued examination of the application requested by the applicant under section 132(b), beginning on the date on which a Request for Continued Examination was filed, October 1, 2008, and ending on the date the patent issues.

The amount of the Adjustment under 37 C.F.R. §1.702(b) is calculated from November 16, 2004 (*i.e.*, the day after the date that is three years from the date that the National Stage commenced), through the day before the date the Request for Continued Examination was filed, *i.e.* September 30, 2008, subtracting only time legitimately attributable to Applicant delay. Applicants submit that the Adjustment under 37 C.F.R. §1.702(b) is 1415 days. However, Applicants note that from December 3, 2004 though January 17, 2007, which is 776 days, delay under 37 C.F.R. 1.702(a) and 37 C.F.R. 1.702(b) overlap

Applicants have calculated the Patent Term Adjustment based on 37 C.F.R. 1.702(a), 37 C.F.R. 1.702(b) and 37 C.F.R. 1.704 through the mailing of the Notice of Allowance. The total calculation of Patent Term Adjustment is as follows: Office delay under 37 CFR 1.702(a) is $776+18 = 794$ days; Office Delay under 37 CFR 1.702(b) is 1415 days; and Applicant delay under 37 CFR 1.704(c) is: $51+28+141+4+23 = 247$ days; overlap of 776 days, adjustment is $794+1415-247-776 = 1186$ days.

Applicants reserve the right to request any further patent term adjustment based on the actual issue date of the instant application.

If the Office would like to discuss any aspect of this filing, the Office representative assigned to process this request is welcome to call the undersigned attorney. No additional fee is believed to be due by submission of this paper. However, the Office is authorized to charge any such fees, or to credit any overpayment in fees to Deposit Account No. **50-0311**, Customer Number **30623**, Attorney Docket No. 24434-001 NATL.

Respectfully submitted,

/Erica R. Carlson/

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Date: September 21, 2009

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| 09/980,661 | METHOD AND DEVICE FOR DETERMINING THE CONCENTRATION OF A SUBSTANCE IN BODY LIQUID | 09-18-2009::16:00:37 |
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 09/980,661

| | | | |
|------------------------------|------------|--------------------------------------|-----|
| Filing or 371(c) Date: | 10-02-2003 | USPTO Delay (PTO) Delay (days): | 794 |
| Issue Date of Patent: | - | Three Years: | - |
| Pre-Issue Petitions (days): | +0 | Applicant Delay (APPL) Delay (days): | 196 |
| Post-Issue Petitions (days): | +0 | Total PTA (days): | 598 |
| USPTO Adjustment(days): | +0 | Explanation Of Calculations | |

Patent Term Adjustment History

| Date | Contents Description | PTO(Days) | APPL(Days) |
|------------|--|-----------|------------|
| 09-01-2009 | Mail Notice of Allowance | 18 | |
| 07-28-2009 | Notice of Allowance Data Verification Completed | ⬆ | |
| 07-28-2009 | Document Verification | ⬆ | |
| 01-15-2004 | Reference capture on IDS | ⬆ | |
| 01-15-2004 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 05-13-2009 | Date Forwarded to Examiner | ⬆ | |
| 04-14-2009 | Response after Non-Final Action | | 23 |
| 04-14-2009 | Request for Extension of Time - Granted | | ⬆ |
| 12-22-2008 | Mail Non-Final Rejection | | ⬆ |
| 12-21-2008 | Non-Final Rejection | | |
| 10-08-2008 | Date Forwarded to Examiner | | |
| 10-08-2008 | Date Forwarded to Examiner | | |
| 10-01-2008 | Request for Continued Examination (RCE) | | 4 |
| 10-08-2008 | DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA) | | ⬆ |
| 10-01-2008 | Request for Extension of Time - Granted | | ⬆ |
| 10-01-2008 | Workflow - Request for RCE - Begin | | ⬆ |
| 06-27-2008 | Mail Final Rejection (PTOL - 326) | | ⬆ |
| 06-23-2008 | Final Rejection | | |
| 04-10-2008 | Date Forwarded to Examiner | | |
| 03-19-2008 | Response after Non-Final Action | | 141 |
| 03-19-2008 | Request for Extension of Time - Granted | | ⬆ |
| 02-20-2008 | Miscellaneous Incoming Letter | | ⬆ |
| 01-24-2008 | Mail Notice of Informal or Non-Responsive Amendment | | ⬆ |
| 11-05-2007 | Date Forwarded to Examiner | | ⬆ |
| 10-30-2007 | Informal or Non-Responsive Amendment after Examiner Action | | ⬆ |
| 10-30-2007 | Response after Non-Final Action | | ⬆ |
| 10-01-2007 | Information Disclosure Statement (IDS) Filed | | |
| 08-09-2007 | Mail Non-Final Rejection | | |
| 08-06-2007 | Non-Final Rejection | | |
| 05-31-2007 | Miscellaneous Incoming Letter | | |

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|------------|---|-----|----|
| 01-15-2004 | Information Disclosure Statement considered | | |
| 01-15-2004 | Information Disclosure Statement (IDS) Filed | | |
| 05-23-2007 | Date Forwarded to Examiner | | |
| 05-15-2007 | Response after Non-Final Action | | 28 |
| 05-15-2007 | Request for Extension of Time - Granted | | ⬆ |
| 01-17-2007 | Mail Non-Final Rejection | 776 | |
| 01-08-2007 | Non-Final Rejection | ⬆ | |
| 07-28-2006 | Information Disclosure Statement considered | ⬆ | |
| 08-02-2004 | Information Disclosure Statement considered | ⬆ | |
| 07-28-2006 | Reference capture on IDS | ⬆ | |
| 07-28-2006 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 07-28-2006 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 06-26-2006 | Case Docketed to Examiner in GAU | ⬆ | |
| 08-02-2004 | Reference capture on IDS | ⬆ | |
| 08-02-2004 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 08-02-2004 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 11-09-2004 | Transfer Inquiry to GAU | ⬆ | |
| 06-17-2004 | Reference capture on IDS | ⬆ | |
| 06-17-2004 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 06-17-2004 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 06-08-2004 | Mail-Petition Decision - Dismissed | ⬆ | |
| 06-04-2004 | Petition Entered | ⬆ | |
| 03-03-2004 | Reference capture on IDS | ⬆ | |
| 03-03-2004 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 03-03-2004 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 01-16-2004 | Reference capture on IDS | ⬆ | |
| 12-10-2003 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 12-10-2003 | Information Disclosure Statement (IDS) Filed | ⬆ | |
| 01-16-2004 | IFW TSS Processing by Tech Center Complete | ⬆ | |
| 12-28-2003 | Cleared by OIPE CSR | ⬆ | |
| 10-02-2003 | 371 Completion Date | ⬆ | |
| 11-19-2003 | Application Dispatched from OIPE | | |
| 11-19-2003 | Notice of DO/EO Acceptance Mailed | | |
| 10-02-2003 | Additional Application Filing Fees | | |
| 10-02-2003 | A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant | | |
| 10-02-2003 | Drawing Preliminary Amendment | | |

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